

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

OPI DATE 11/11/91

APPLN. IN

55518 / 90

AOJP DATE 19/12/91

PCT NUMBER PCT/FR90/00285

PCT

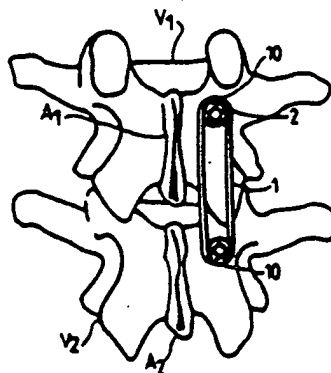
DEMANDE INTERNATIONALE PUBLIEE EN VERTU DU TRAITE DE COOPERATION EN MATIERE DE BREVETS (PCT)

(51) Classification internationale des brevets ⁵ : A61F 2/44, A61B 17/60	A1	(11) Numéro de publication internationale: WO 91/16018 (43) Date de publication internationale: 31 octobre 1991 (31.10.91)
(21) Numéro de la demande internationale: PCT/FR90/00285 (22) Date de dépôt international: 19 avril 1990 (19.04.90) (71)(72) Déposants et inventeurs: BREARD, Francis, Henri (FR/FR); 13, rue Friant, F-75014 Paris (FR). GRAF, Henry (FR/FR); 12, quai Jules-Courmont, F-69002 Lyon (FR). (74) Mandataire: CABINET MALEMONT; 42, avenue du Président-Wilson, F-75116 Paris (FR). (81) Etats désignés: AU, JP, SU. Publiée <i>Avec rapport de recherche internationale.</i>	<div style="font-size: 48px; font-weight: bold;">650620</div>	

SUPPLE

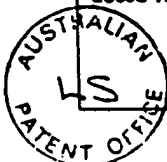
(54) Title: ~~PLEXIBLE~~ INTERVERTEBRAL STABILIZER, AND METHOD AND APPARATUS FOR DETERMINING OR CONTROLLING ITS TENSION BEFORE IT IS PLACED ON THE BACK BONE

(54) Titre: STABILISATEUR INTER-VERTEBRAL SOUPLE AINSI QUE PROCEDE APPAREILLAGE POUR LA DETERMINATION OU LE CONTROLE DE SA TENSION AVANT MISE EN PLACE SUR LE RACHIS



(57) Abstract

An intervertebral stabilizer comprising one or more ^{supple} ~~flexible~~ ligament(s) (1, 1a, 1b), each of which has a device for hooking onto two respective vertebrae and/or is linked to two securing elements (2, 3) such as screws (2, 3) with free heads (4) which can be implanted in respective vertebrae (V₁, V₂). A method and an apparatus for determining or controlling the tension in an intervertebral stabilizer before it is placed on the backbone are also described. The method, which is carried out after the implantation in each of said vertebrae (V₁, V₂) of a respective rigid rod extending outside the patient's body, involves, for each pair of neighbouring rods, immobilizing both said rods in an initial position and, if the pain to be eliminated by said stabilizer persists, altering the distance between said rods. Then, said rods are immobilized in their new positions and a new pain test is carried out. These operations may be repeated until said pain disappears, and the correct length of the ligament is deduced from the final distance between said rods.



(57) Abrégé La présente invention concerne un stabilisateur inter-vertébral qui comprend un ou plusieurs ligament(s) souple(s) (1, 1a, 1b) chacun muni de moyens d'accrochage à deux vertèbres respectives et/ou associées à deux organes de retenue (2, 3), tels que des vis (2, 3) à tête libre (4) implantables chacune dans une vertèbre respective (V₁, V₂). La présente invention a également pour objet un procédé, et l'appareillage associé, pour déterminer ou contrôler la tension d'un tel stabilisateur inter-vertébral avant sa mise en place sur le rachis. Ce procédé, mis en œuvre après implantation dans chacune des vertèbres concernées (V₁, V₂), d'une tige rigide respective se prolongeant hors du corps du patient, consiste, pour chaque paire de tiges voisines, à immobiliser les deux tiges dans une position initiale et, en cas de persistance de la douleur dont la cause doit être supprimée par le stabilisateur, à modifier la distance entre les tiges, puis à immobiliser ces dernières dans leur nouvelle position relative et à effectuer à nouveau le test de douleur, ce cycle d'opérations étant éventuellement répété jusqu'à ce que la dite douleur disparaisse, la longueur à donner au ligament étant déduite de la distance alors atteinte entre les deux tiges.

UNIQUEMENT A TITRE D'INFORMATION

Codes utilisés pour identifier les Etats parties au PCT, sur les pages de couverture des brochures publiant des demandes internationales en vertu du PCT

AT	Autriche	FI	Finlande	ML	Mali
AU	Australie	FR	France	MN	Mongolie
BB	Barbade	GA	Gabon	MR	Mauritanie
BE	Belgique	GB	Royaume-Uni	MW	Malawi
BF	Burkina Faso	GN	Guinée	NL	Pays-Bas
BG	Bulgarie	GR	Grèce	NO	Norvège
BJ	Bénin	HU	Hongrie	PL	Pologne
BR	Brazil	IT	Italie	RO	Roumanie
CA	Canada	JP	Japon	SD	Soudan
CF	République Centrafricaine	KP	République populaire démocratique de Corée	SE	Suède
CG	Congo	KR	République de Corée	SN	Sénégal
CH	Suisse	LI	Liechtenstein	SU	Union soviétique
CI	Côte d'Ivoire	LK	Sri Lanka	TD	Tchad
CM	Cameroun	LU	Luxembourg	TC	Togo
DE	Allemagne	MC	Monaco	US	Etats-Unis d'Amérique
DK	Danemark	MG	Madagascar		
ES	Espagne				

Supple Intervertebral stabiliser as well as process and apparatus
for determining or verifying its tension before installation on the
spinal column.

5 The present invention relates to an intervertebral stabiliser to be installed between at least between two vertebrae to correct defects in the spinal column.

Throughout the specification and claims, the words supple and flexible are utilised, however, different meanings are accorded to these two words. The word "supple" is related to objects that can change shape according to forces in all directions and keep that shape until other forces are applied: they can be easily folded and unfolded without breaking or damaging. The word "flexible" on the other hand is related to objects that can change their shape according to certain directions, however, will return to their initial position. They can be curved but can't fold and unfold.

Inter-vertebral stabilisers currently used to attenuate the often painful effects of diseases of the spinal column, such as scolioses, nucleus pulposus herniations or lumbar instabilities, take the form of metal plates or rods that are fixed to the vertebrae or to their spines, along the affected section of the spinal column, which has the drawback of completely immobilizing the vertebrae, hence of restricting or even completely preventing flexional or torsional movements of the patient's trunk.

10 The present invention has for its objective the provision of an inter-vertebral stabiliser either implanted or capable of being implanted which will overcome the aforementioned difficulties.

In preferred aspects the present invention also aims at providing a process for determining or verifying tension of such inter-vertebral stabilisers according to the present invention and providing apparatus for carrying out these processes.

Accordingly, the present invention provides an inter-vertebral stabiliser adapted to be installed between at least two successive vertebrae comprising one or more supple ligaments and two retaining elements, each said retaining element having a free head for fastening a said ligament thereto, and each said ligament being provided with fastening means for fastening it to a respective one of said retaining elements whereby, in use, said retaining elements are implanted into a respective said vertebrae and at least one said ligament is fastened to said retaining elements.

According to a further aspect, the present invention provides an inter-vertebral stabiliser installed between at least two successive vertebrae, characterised in that it comprises one or more supple ligaments, each said ligament being provided with fastening means fastening the ligament between said two vertebrae with two retaining elements, each of the two retaining elements being implanted in a respective one of said vertebrae. In accordance with a still further aspect, the present invention provides an inter-vertebral stabiliser when installed between at least two successive vertebrae, said stabiliser comprising one or more supple ligaments, each ligament being provided with means for fastening it to the two respective vertebrae.

Advantageously, the or at least one supple ligament has the general form of a closed loop or, alternatively, is provided with a ring or a closed loop at each end thereof, whereby the ends of each ligament constitute said fastening means through which said ligament can be fastened by hanging to a spine or any other protrusion of a respective vertebra. When retaining elements are provided, each of them, being preferably a screw, is advantageously formed with a free head for fastening a respective end of the corresponding ligament.

There is thus obtained a supple or semi-elastic inter-vertebral stabiliser which, according to its mode of implantation, on one side only or on both sides of the spines of the vertebrae concerned, on the front face or the rear face thereof, with a single ligament or with several ligaments chained together or even crossed with each other, makes it possible to compensate for all sorts of defects

or deformations of the spinal column by permitting sufficient clearance between the vertebrae not to hinder the patient in the flexional or torsional movements of

5 his trunk.

2
3
4

5
6
7
8
9

10
11
12

Apart from this main advantage, the inter-vertebral stabilizer according to the invention is extremely simple to install: it suffices to engage the end of each ligament around for example two vertebral spines or two screws pre-implanted in the vertebrae.

5 To prevent any slipping of the ligament once it has been put in place, in the case where retaining elements, such as screws, are used, provisions is also advantageously made for fitting onto each retaining element, a removable cap that is radially over-dimensioned in relation to the head of the retaining element. The same effect can be obtained by alternatively providing the head
10 of each retaining element with a lateral projection for retaining the ligament.

Before putting the stabilizer in place on the spinal column, its tension, i.e. the length at rest of the, or of each, ^{supple} ~~flexible~~ ligament, will naturally have to be determined precisely in accordance with the seriousness of the
15 defect to be corrected and, for this purpose, the present invention proposes a process implemented after implanting, in each of the vertebrae concerned and at the point at which the corresponding ligament is to be fixed, a corresponding rigid rod extending out of the patient's body, this process being characterized in that it consists, for each pair of adjacent rods, in
20 immobilizing the two rods at a predetermined distance from one another and, in the event of persistence, after a given time period has elapsed, of the pain the cause of which the stabilizer is intended to remove, in modifying the distance between the rods by a certain pitch and then immobilizing them in their new relative positions and carrying out the pain test once again, this
25 cycle of operations being repeated, if necessary, until the said pain disappears, the length at rest to be given to the ligament then being deduced from the value of the distance then reached between the two rods.

This process can also be implemented for verifying and modifying the tension of one or more ligaments already in place on the spinal column, when the
30 patient experiences pain after a less or more long period of use.

Another object of the invention is to provide an apparatus for determining

the tension of an inter-vertebral stabilizer according to the invention before it is put into place on the spinal column, the said apparatus being characterized in that it comprises a set of at least two rods each having an end for implantation in the corresponding vertebra, these rods being associated at least with a rigid link of adjustable length designed to join them together at a point remote from their implantation ends.

According to a preferred embodiment, the implantation end of each rod is constituted by an element having a head onto which is removably fitted an extension piece forming the remaining portion of the rod, designed to receive the rigid length-adjustable link.

Once the operation of determining the tension of the inter-vertebral stabilizer has been completed, the end elements of the rods, which will preferably be screws, can be advantageously held in place in the vertebrae to form the ligament retaining elements, and the ligament, after being produced to the length calculated using the process according to the invention, can easily be engaged around the said screws by sliding along the extension pieces before they are removed.

The rigid length-adjustable link can, for its part, take various forms, the simplest being that of a thin bar and two collars that can be fitted respectively onto the two rods and are provided with means for slidably supporting the bar between them, a bar locking member being provided on each collar.

Advantageously, the apparatus according to the invention further comprises an instrument for determining the length at rest of the ligament, which is formed by two crossed legs articulated on one another at their middle, the ends of the legs located on the same side of the articulation each having a substantially semi-circular contacting portion, which is applied onto the head of the corresponding retaining element. In this way, it is possible to determine between the other ends of the two legs of this instrument the length required for the ligament to be implanted, which can be measured using a graduated rule.

Embodiments of the inter-vertebral stabilizer according to the invention, together with a process and an apparatus for determining their tension, will now be described in greater detail, but non limitatively, with reference to the accompanying drawings, wherein:

- figure 1 shows a side view in partial cross-section of the inter-vertebral stabilizer according to the first embodiment of the invention;

- figure 2 is a front view of an inter-vertebral stabilizer according to the second embodiment of the invention;

5 - figures 2a and 2b show alternative embodiments of the stabilizer of figure 2;

- figures 3a, 3b and 3c illustrate one of the ligament retaining elements of the stabilizer of figure 1;

0 - figures 4a and 4b show, in longitudinal cross-sectional view and in front view respectively, one of the ligament retaining elements of the stabilizer of figure 2;

- figure 5 is a side view, in partial cross-section, of the apparatus according to the invention, represented in use on two adjacent vertebrae;

- figure 6 is a cross-sectional view along line VI-VI of figure 5;

5 - figure 7 illustrates, in its position of use, a supplementary accessory of this apparatus, designed to determine the length at rest of the ligament; and

- figure 8 represents the apparatus of figure 5 as used for the insertion of the ^{supple}~~flexible~~ ligament around the retaining elements.

0 Figure 1 represents two adjacent vertebrae, V1, V2, of a patient's spinal column, linked by an inter-vertebral stabilizer according to the invention, which is composed of a ^{supple}~~flexible~~ ligament 1 in the form of a closed loop and of two screws 2,3 each implanted in a corresponding vertebra to retain ligament 1 between them, said ligament being simply engaged around the widened cylindrical heads 4 of the screws, emerging from the vertebrae. Ligament 1 is an artificial ligament made of "Dacron" (registered trade-mark) or of any other ^{supple}~~flexible~~ plastics material, ~~having an added direction flexibility.~~

5 As more clearly shown in the longitudinal cross-sectional and front views of figures 3b and 3c, the head 4 of each screw comprises an axial blind hole 5 having a hexagonal cross-section, in which a hexagonal key can be engaged in order to implant the screw in the corresponding vertebra.

0 After ligament 1 has been put into place around the screws thus implanted, hole 5 of each of said screws is closed using a flat circular cap or plug 6, shown alone in figure 3a, said cap, the diameter of which is substantially

LIAN
5 14

larger than that of head 4 of the screw, being screwed by means of a central pin 7 with a threaded end into a threaded bore 8 opening in the bottom of hole 5. To accomplish this screwing operation, use is made of a special key cooperating with two slots, 9,9a, formed on the periphery of each cap 6. Alternatively, each cap may be provided with a central hexagonal bore and screwed on the head 4 of the corresponding screw by using a hexagonal key engaged in this bore. By projecting radially right around the corresponding heads 4 of the screws, the two caps 6 preclude any likelihood of ligament 1 slipping off the said heads, as illustrated in figure 1.

The caps 6 are particularly useful when the inter-vertebral stabilizer according to the invention comprises several supplementary ^{supple} ~~flexible~~ ligaments, such as illustrated at 1a and 1b in figure 1, chained together with first ligament 1, on the vertebrae preceding and following the two designated by V1,V2, with the help of the same number of supplementary retaining screws.

In the case illustrated in figure 2, in which only one ligament 1 in the form of a closed loop will have to be interposed between only two successive vertebrae V1,V2, the head 4 of each screw 2 or 3 can be provided alternatively with a lateral projection 10 of suitable height, as represented in profile and in front view in figures 4a and 4b. In this case, it will be necessary first of all to implant the two screws 2,3 by orientating their projections 10 opposite one another so that ligament 1 can be then slid without any impediment around their heads 4, after which the screws will be given an additional half-turn to place projections 10 in their ligament retaining positions, as shown in figure 2.

The inter-vertebral stabilizer according to the invention makes it possible, according to its positioning, to combat numerous painful diseases affecting the spinal column. The stabilizer shown in figures 1 and 2 is put into place on the rear face of vertebrae V1,V2 and on one side only of their spines A1,A2. However, depending on the type of disease to be treated, it is possible to use two stabilizers according to the invention, mounted on either side of vertebral spines A1,A2 or crossed between the two vertebrae V1,V2, on the front or rear face thereof. In all cases, however, it is necessary to determine the tension of the stabilizer, i.e. the length at rest of its ligament 1, accurately before it is installed, as a function of the seriousness of the defect to be corrected.

For this purpose, the present invention proposes a process and an apparatus for its implementation, which will now be described with reference to figures 5 to 8.

As it can be seen, the basic accessories of this apparatus are two rigid rectilinear rods, 11,12, which are fixed in the respective vertebrae V1,V2 by their ends which, in the preferred embodiment represented in figure 5, are formed by screws 2,3 of what is to become the stabilizer. Each screw is implanted in the way described above after a local surgical incision has been made in the patient's back in front of each vertebra for uncovering it. Each rod 11,12 is completed by a cylindrical extension piece 13 having a threaded end 14, which is fitted onto the head 4 of the corresponding screw by screwing into its threaded bore 8 after removal of cap 6. For this purpose, the free opposite end of each extension piece 13 is provided with a hexagonal head 23 suitable for receiving a tightening key. It will also be noted that each extension piece 13 has a root 13a which flares progressively until its diameter is substantially equal to that of the head of screw 4 onto which it is fitted.

The two rods 11,12 being thus implanted so as to extend out from the patient's back D, they are joined in the vicinity of their free ends 14 by a rigid link 15 of adjustable length and, by means of the latter, the distance between the rods is adjusted to a value that is predetermined as a function of the nature and the seriousness, previously diagnosed, of the defect to be corrected on the spinal column.

After the two rods have been thus immobilized in this initial position, the incisions in the patient's back are closed up and the patient is made to undergo a test which consists in verifying whether, at the end of a given period, possibly one to two days, the patient still experiences pain in the affected area of the spinal column. If this is the case, the spacing between rods 11,12 is slightly modified, generally for bringing them closer to one another (compression), by acting on the length of link 15, and the pain test is repeated over substantially the same period of time as before.

This dual operation will be repeated if necessary, preferably with a constant pitch of change in the spacing of rods 11, 12, until the patient no longer experiences any pain in the back. Once this result has been achieved, the length

at rest required for the ligament to be implanted between the vertebrae is measured or calculated with maximum accuracy.

In practice, the maximum number of successive cycles of verifying operations leading to the elimination of pain will be three and, if the pain proves to persist after these three cycles of operations, this will mean that the defect that causes it is not present in the pair of vertebrae tested and the process according to the invention will then have to be applied to the following pair of vertebrae or successively on the following pair(s) of vertebrae, until the pain disappears.

Of course, when several ^{supple} ~~flexible~~ ligaments are to be chained together, such as 1, 1a and 1b (figure 1), over a long section of the spinal column, the above described process will be applied simultaneously to all the successive vertebrae to be treated, using as many rods 11,12 as there are vertebrae and joining them two by two using length adjustable links such as 15.

This link, which is more clearly represented in figure 6, is in fact formed here by a thin cylindrical bar 16 retained on two collars 17,18, each of which is fixed to a corresponding rod 11, 12 by means of a lock screw 19. Bar 16 is more precisely housed so as to be able to slide freely in a groove 20 of each of collars 17,18 and is locked therein, after the spacing of the rods has been adjusted, by head 21 of lock screw 19 of the corresponding collar. Alternatively, of course, link 15 can take the form of a device with threaded rods with reversed screw pitches, which could even be fitted with a system for directly measuring the spacing between rods 11,12.

The length to be allocated to the ligament can be derived, by a trigonometrical calculation, from the distance d measured, for example near link 15, between rods 11,12 immobilized in the right position. According to an additional feature of the invention, however, it is possible, as an alternative, to measure directly the length to be allocated to ligament 1 between heads 4 of screws 2,3 by using an instrument which will now be described, together with its mode of use, with reference to figure 7.

As it can be seen, this instrument 24 for determining the length of the ligament takes the general form of a "pair of scissors" and is more specifically, formed by two legs, 25,26, of the same length, which cross in their middle and

are articulated on one another at their point of crossing by means of a lock screw 30. On the same side of this articulation 30, the ends of the two legs 25, 26 carry a contacting piece, 28 or 29, which is substantially semi-circular and has a inner diameter slightly greater than that of the heads 4 of retaining screws 2, 3. These contacting pieces 28 and 29 are facing each other and their inner arcuate face is flush with the inner side of the corresponding leg 25 or 26 of instrument 24. At their opposite ends, legs 25, 26 are each provided with a ring, 31, 32, to accommodate a finger.

To measure the length of the ligament using the said instrument 24, an incision is first made in the patient's back as far as vertebrae V1, V2 are uncovered. Then, after having loosened screw 30 and by holding instrument 24 in one hand by means of rings 31, 32, each of contacting pieces 28 or 29 is placed on a respective rod 11 or 12 and the instrument is caused to slide along these rods until the contacting pieces are bearing on the ends of heads 4 of screws 2, 3. Screw 30 is then re-tightened and, using a graduated rule 33, the distance between the free ends 25a, 26a of legs 25, 26 of instrument 24 is measured and the value of the length required for the ligament to be implanted between retaining screws 2, 3 is thus obtained directly.

After this length measurement, ligament 1 or each of ligaments 1, 1a, 1b to be implanted is prepared from a tubular artificial ligament which is flattened and sewn back on itself. After link 15 has been removed, the ligament thus formed into a loop is passed around the two extension pieces 13 and slid along them up to screws 2, 3, around the heads 4 of which it is then engaged with the help, if necessary, of a special semi-cylindrically shaped tool 22, as shown in figure 8. Extension pieces 13 are then removed, caps 6 are screwed onto the heads of screws 2, 3 (figure 1) or the latter are orientated in such a way as to place their projections 10 in ligament retaining position (figure 2); then the incisions in the patient's back is definitively closed up.

It goes without saying that numerous modifications can be made in the inter-vertebral stabilizer and in the apparatus that have just been described.

For instance, according to an alternative embodiment, shown on figure 2a, of the stabilizer of Figure 2, the ligament 1c is in the form of a single segment 40 to each end of which a metallic ring 41 or 42 is attached, with which the

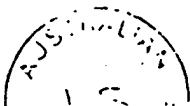
ligament can be fastened by hanging over the head 4 of a respective retaining screw 2 or 3.

According to another alternative embodiment shown on figure 2b, the ligament 1d of the stabilizer, having the form of a closed loop, is passed through himself for defining a first end loop 43 which is engaged around the spine A_1 of a respective vertebra V_1 . At its second end, the ligament 1d is placed around spine A_2 of the lower vertebra V_2 , then re-passed through himself for forming a second end loop 45 after insertion of a locking pin 44. Spines A_1 and A_2 here play the role of the retaining screws 2,3, but it goes without saying that ligament 1d of figure 2b can also be associated with such screws, as those 1 and 1c of figures 2 and 2a. Inversely, ligaments 1 and 1c of figures 2 and 2a can be fastened by an hanging connection directly over spines A_1 and A_2 of vertebrae V_1 and V_2 , without the use of retaining screws, as the ligament 1d of figure 2b. Of course, a chained arrangement of a plurality of ligaments, as the one shown on figure 1, may also be obtained with the embodiments of figures 2a and 2b, by means of pre-implanted retaining screws or by direct fastening over the spines of the vertebrae concerned.

For their part, screws 2,3 could be replaced by any other retaining element capable of being implanted in a vertebra and provided with a free head for fastening a ligament end thereover.

Furthermore, rods 11, 12 of the apparatus of the present invention can be made in a single piece, the two-piece form of embodiment described above being preferable, however, when ligament retaining elements, such as screws, are used because, in this case, it precludes the need to reimplant said retaining elements after the preliminary operation for determining the tension of the stabilizer.

It should further be pointed out that the screws or other retaining elements 2,3, their caps 6 and rods 11,12 will preferably be made from a bio-compatible metallic alloy.



THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS.

1. An inter-vertebral stabiliser adapted to be installed between at least two successive vertebrae comprising one or more supple ligaments and two retaining elements, each said retaining element having a free head for fastening a said ligament thereto, and each said ligament being provided with fastening means for fastening it to a respective one of said retaining elements whereby, in use, said retaining elements are implanted into a respective said vertebrae and at least one said ligament is fastened to said retaining elements.
2. An inter-vertebral stabiliser installed between at least two successive vertebrae, characterised in that it comprises one or more supple ligaments, each said ligament being provided with fastening means fastening the ligament between said two vertebrae with two retaining elements, each of the two retaining elements being implanted in a respective one of said vertebrae.
3. The inter-vertebral stabiliser according to claim 1 or claim 2, characterised in that the or at least one supple ligament has the general form of a closed loop, the ends of which constitute said fastening means.
4. The inter-vertebral stabiliser according to claim 1 or claim 2, characterised in that the or at least one supple ligament is provided, at each end thereof, with a ring or a closed loop constituting said fastening means.
5. The inter-vertebral stabiliser according to claim 1, characterised in that each of the retaining elements is provided with a removable cap, radially over-dimensioned in relation to the head of the retaining element, on which it can be fitted.
6. The inter-vertebral stabiliser according to claim 1, characterised in that the head of each retaining element is provided with a lateral projection for retaining the ligament.

7. An inter-vertebral stabiliser when installed between at least two successive vertebrae, said stabiliser comprising one or more supple ligaments, each ligament being provided with means for fastening it to the two respective vertebrae.

8. Process for determining or verifying the tension of an inter-vertebral stabiliser according to any one of claims 1 to 7, before its installation on the spinal column, this process, which is implemented after the implantation, in each of the vertebrae concerned and at the point at which the corresponding ligament is to be fixed, of a corresponding rigid rod extending out of the patient's body, being characterised in that it consists, in the case of each pair of adjacent rods, in immobilising the two rods at a predetermined distance from one another and, in the event where the pain, the cause of which is to be removed by the stabiliser, is persisting after a given time period has elapsed, in modifying the distance between the rods by a certain pitch, and then in immobilising the latter in their new relative positions and in carrying out the pain test once again, this cycle of operations being repeated, if necessary, until the said pain disappears, the length at rest to be given to the ligament then being deduced from the value of the distance then attained between the two rods.

9. Apparatus for implementing the process according to claim 8, for determining or verifying the tension of an inter-vertebral stabiliser according to one of claims 1 to 8, before it is put into place on the spinal column, characterised in that it comprises a set of at least two rods each having an end for implanting in the respective vertebra, the said rods being associated with at least one rigid link of adjustable length designed to join them at a point remote from their implantation ends.

10. The apparatus according to claim 9, characterised in that the implantation end of each rod is constituted by the corresponding retaining element of the ligament of the said stabiliser and each of the rods is completed by a removable extension piece fitting onto the head of said retaining element.



11. The apparatus according to claim 10, characterised in that the said length-adjustable rigid link comprises a thin bar and two collars that can be fitted respectively on the two rods and are provided with means for supporting the bar slidingly between them, an element for locking the bar being provided on each collar.

12. The apparatus according to any one of claims 9 to 11, characterised in that it comprises an instrument for determining the length at rest of the ligament, which is formed by two crossed legs articulated on one another at their middle, the ends of the legs located on the same side of the articulation each having a substantially semi-circular contacting portion.

DATED this 2nd day of May, 1994

FRANCIS HENRI BREARD and HENRY GRAF

WATERMARK PATENT & TRADEMARK ATTORNEYS
THE ATRIUM
290 BURWOOD ROAD
HAWTHORN VICTORIA 3122
AUSTRALIA

SKP/RJD/BB] (Doc. 33) AU5551890.WPC

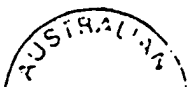
TITLE: ^{Supple}~~Stabilizer~~ inter-vertebral stabilizer together with
process and apparatus for determining its tension
before installation on the spinal column

ABSTRACT OF THE DISCLOSURE

The present invention relates to an inter-vertebral stabilizer comprising one or more ^{supple}~~flexible~~ ligaments (1,1a,1b), each of them being provided with means for fastening it to two respective vertebrae and/or associated with two retaining elements (2,3), such as screws, each of which is suitable for being implanted in a respective vertebra (V1,V2).

The present invention also relates to a process, and the associated apparatus, for determining or verifying the tension of such an inter-vertebral stabiliser before it is put into place on the spinal column. This process consists in implanting, in each of the vertebrae concerned (V1,V2), a corresponding rigid rod extending outside the patient's body and, in each pair of adjacent rods, in immobilizing the two rods in an initial position and, in the event where the pain, the cause of which is to be removed by the stabilizer, is persisting, in modifying the distance between the rods, then in immobilizing the latter in their new relative positions and in repeating the pain test, this cycle of operations being repeated, if necessary, until the said pain disappears, the length to be allocated to the ligament being deduced from the distance then attained between the two rods.

(FIGURE 1)



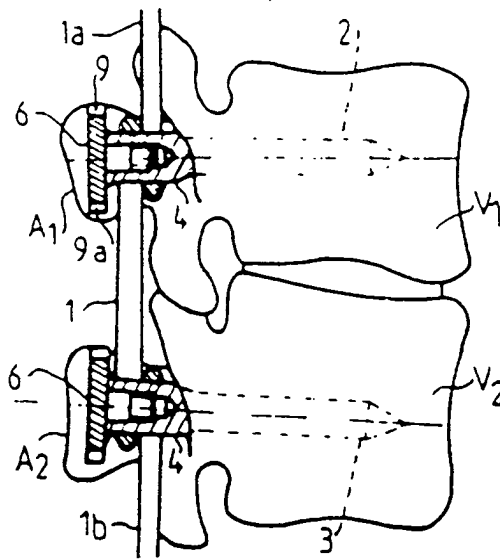


FIG.1

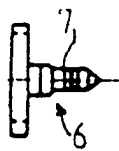


FIG.3a

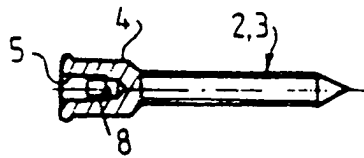


FIG.3b



FIG.3c

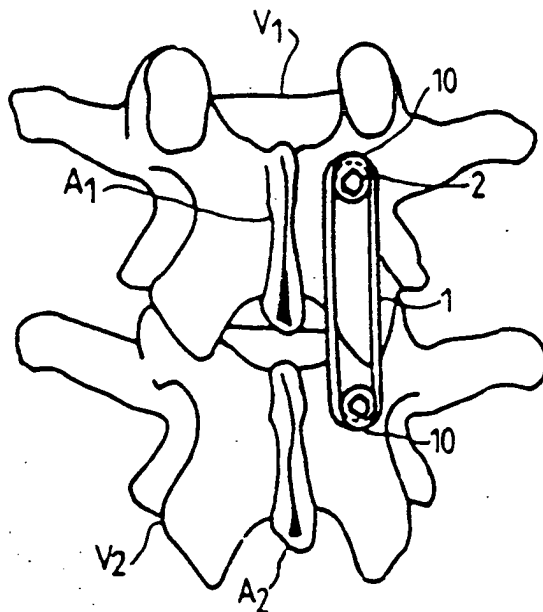


FIG.2

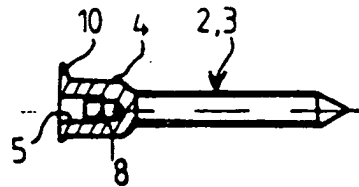


FIG.4a

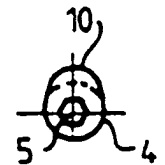


FIG.4b

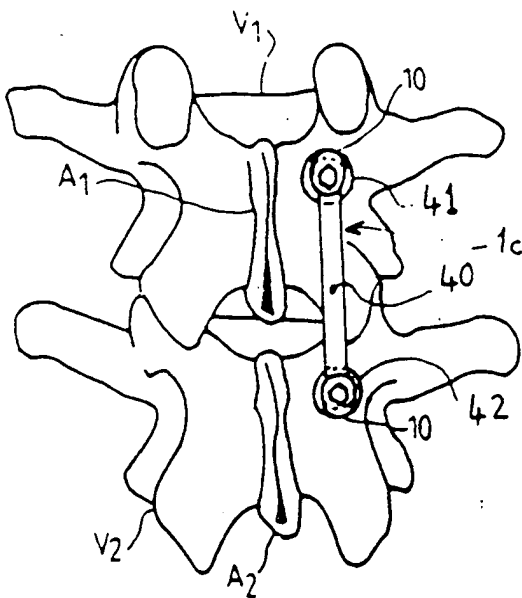


FIG. 2a

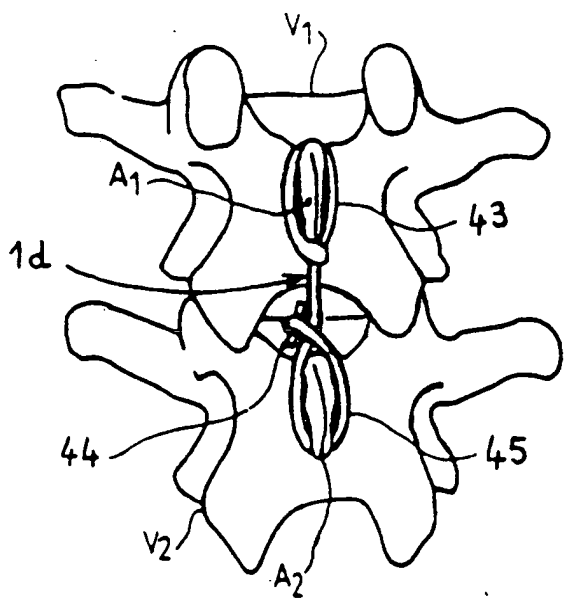


FIG. 2b

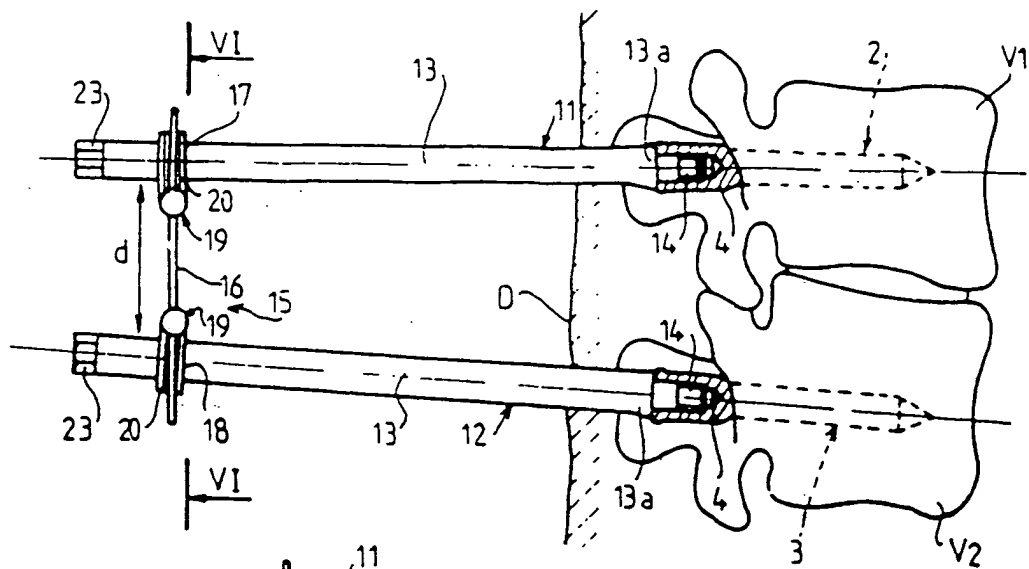


FIG. 5

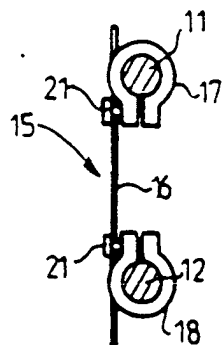


FIG. 6

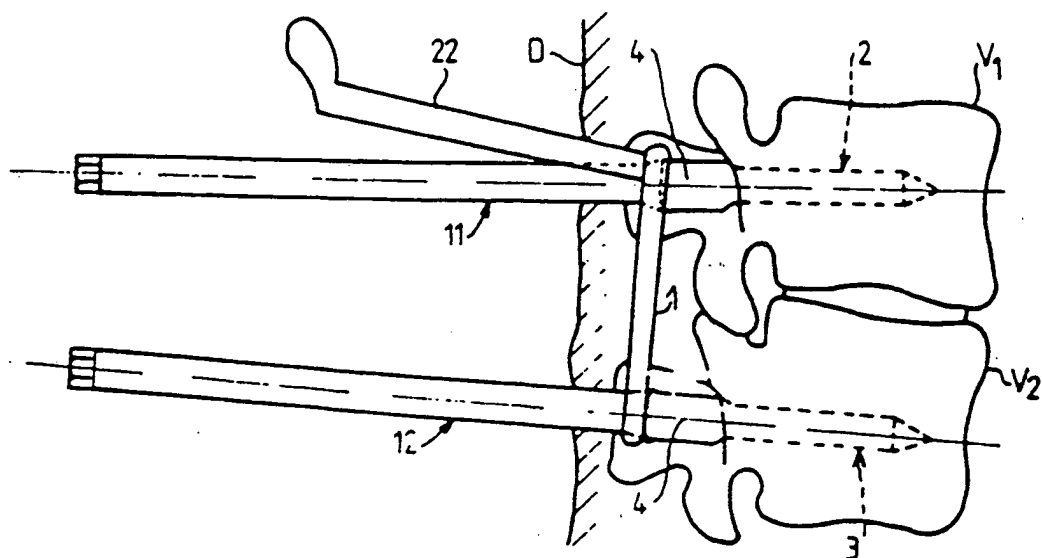


FIG. 8

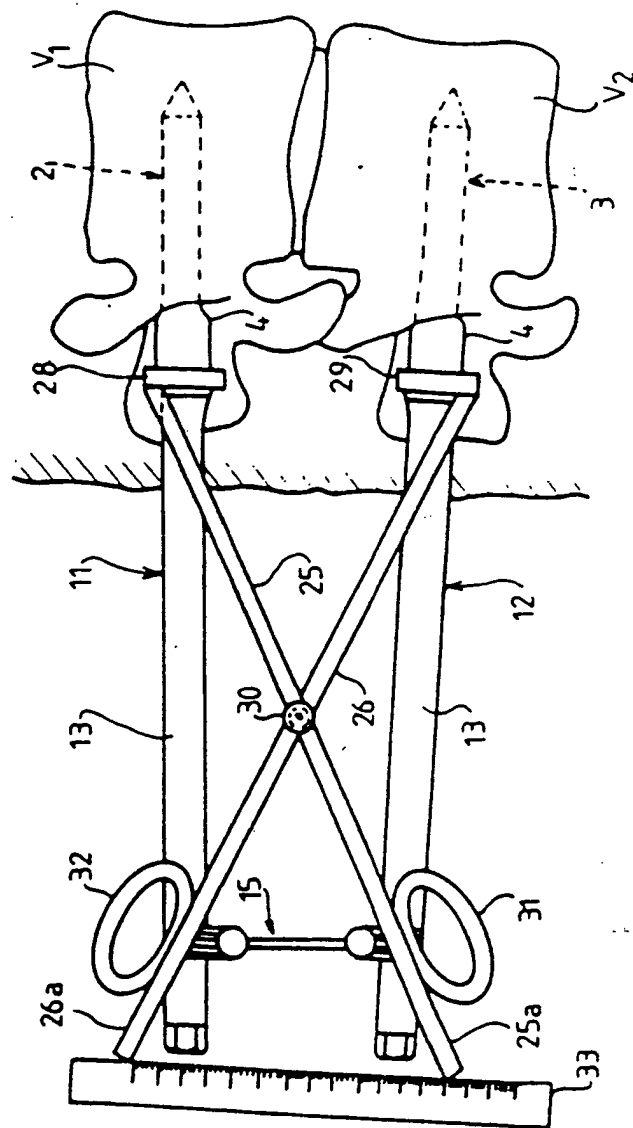


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No. PCT/FR 90/00285

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶ According to International Patent Classification (IPC) or to both National Classification and IPC <div style="text-align: center; font-family: monospace;">Int.Cl.⁵ A 61 F 2/44, A 61 B 17/60</div>																							
II. FIELDS SEARCHED <div style="text-align: right; font-size: small;">Minimum Documentation Searched ⁷</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 35%; border-bottom: 1px solid black; font-size: small;">Classification System</td> <td style="border-bottom: 1px solid black; font-size: small;">Classification Symbols</td> </tr> <tr> <td style="height: 40px; vertical-align: top; font-family: monospace;">Int.Cl.⁵ A 61 F, A 61 B</td> <td></td> </tr> </table> <div style="text-align: center; font-size: x-small;">Documentation Searched other than Minimum Documentation to the extent that such Documents are included in the Fields Searched ⁸</div>			Classification System	Classification Symbols	Int.Cl. ⁵ A 61 F, A 61 B																		
Classification System	Classification Symbols																						
Int.Cl. ⁵ A 61 F, A 61 B																							
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹ <table style="width: 100%; border-collapse: collapse; font-size: x-small;"> <tr> <th style="width: 10%; text-align: left;">Category ¹⁰</th> <th style="width: 70%; text-align: left;">Citation of Document, ¹¹ with indicator, where appropriate, of the relevant passages ¹²</th> <th style="width: 20%; text-align: left;">Relevant to Claim No. ¹³</th> </tr> <tr> <td style="vertical-align: top;">X</td> <td style="vertical-align: top;">US, A, 4743260 (BURTON) 10 May 1988 see the whole document</td> <td style="vertical-align: top;">1-5</td> </tr> <tr> <td style="vertical-align: top;">Y</td> <td style="vertical-align: top;">—</td> <td style="vertical-align: top;">7-10</td> </tr> <tr> <td style="vertical-align: top;">Y</td> <td style="vertical-align: top;">FR, A, 2275679 (CROCK et al.) 16 January 1976 see page 4, lines 18-35; figures 4-6</td> <td style="vertical-align: top;">7-10</td> </tr> <tr> <td style="vertical-align: top;">X</td> <td style="vertical-align: top;">EP, A, 0140790 (PEZE) 8 May 1985 see abstract ; figure 3</td> <td style="vertical-align: top;">1</td> </tr> <tr> <td style="vertical-align: top;">A</td> <td style="vertical-align: top;">FR, A, 1240313 (JUDET) 25 July 1960 see figures</td> <td style="vertical-align: top;">1-4</td> </tr> <tr> <td style="vertical-align: top;">A</td> <td style="vertical-align: top;">WO, A, 88/07357 (KLUGER) 6 October 1988</td> <td></td> </tr> </table>			Category ¹⁰	Citation of Document, ¹¹ with indicator, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³	X	US, A, 4743260 (BURTON) 10 May 1988 see the whole document	1-5	Y	—	7-10	Y	FR, A, 2275679 (CROCK et al.) 16 January 1976 see page 4, lines 18-35; figures 4-6	7-10	X	EP, A, 0140790 (PEZE) 8 May 1985 see abstract ; figure 3	1	A	FR, A, 1240313 (JUDET) 25 July 1960 see figures	1-4	A	WO, A, 88/07357 (KLUGER) 6 October 1988	
Category ¹⁰	Citation of Document, ¹¹ with indicator, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³																					
X	US, A, 4743260 (BURTON) 10 May 1988 see the whole document	1-5																					
Y	—	7-10																					
Y	FR, A, 2275679 (CROCK et al.) 16 January 1976 see page 4, lines 18-35; figures 4-6	7-10																					
X	EP, A, 0140790 (PEZE) 8 May 1985 see abstract ; figure 3	1																					
A	FR, A, 1240313 (JUDET) 25 July 1960 see figures	1-4																					
A	WO, A, 88/07357 (KLUGER) 6 October 1988																						
<div style="display: flex; justify-content: space-between; font-size: x-small;"> <div style="width: 45%;"> <p>¹⁴ Special categories of cited documents: ¹⁵</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="width: 45%;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"A" document member of the same patent family</p> </div> </div>																							
IV. CERTIFICATION <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border-bottom: 1px solid black; font-size: small;">Date of the Actual Completion of the International Search</td> <td style="width: 50%; border-bottom: 1px solid black; font-size: small;">Date of Mailing of this International Search Report</td> </tr> <tr> <td style="height: 30px; vertical-align: bottom; font-family: monospace;">12 October 1990 (12.10.90)</td> <td style="height: 30px; vertical-align: bottom; font-family: monospace;">30 October 1990 (30.10.90)</td> </tr> <tr> <td style="border-bottom: 1px solid black; font-size: small;">International Searching Authority</td> <td style="border-bottom: 1px solid black; font-size: small;">Signature of Authorized Officer</td> </tr> <tr> <td style="height: 30px; vertical-align: bottom; font-family: monospace;">European Patent Office</td> <td></td> </tr> </table>			Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	12 October 1990 (12.10.90)	30 October 1990 (30.10.90)	International Searching Authority	Signature of Authorized Officer	European Patent Office														
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report																						
12 October 1990 (12.10.90)	30 October 1990 (30.10.90)																						
International Searching Authority	Signature of Authorized Officer																						
European Patent Office																							

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

FR 9000285

SA 36737

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 23/10/90. The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A- 4743260	10-05-88	None	
FR-A- 2275679	16-01-76	GB-A- 1519139	26-07-78
EP-A- 0140790	08-05-85	FR-A, B 2553993	03-05-85
		JP-A- 60111651	18-06-85
		US-A- 4697582	06-10-87
FR-A- 1240313		None	
WO-A- 8807357	06-10-88	DE-A- 3711091	13-10-88
		EP-A- 0316371	24-05-89

EPO FORM 1007

For more det: about this annex : see Official Journal of the European Patent Office, No. 12/82

RAPPORT DE RECHERCHE INTERNATIONALE

Demande internationale N° PCT/FR 90/00285

I. CLASSEMENT DE L'INVENTION (si plusieurs symboles de classification sont applicables, les indiquer tous) * Selon la classification internationale des brevets (CIB) ou à la fois selon la classification nationale et la CIB CIB ⁵ : A 61 F 2/44, A 61 B 17/60		
II. DOMAINES SUR LESQUELS LA RECHERCHE A PORTE Documentation minimale consultée ? Système de classification Symboles de classification <div style="display: flex; justify-content: space-between; padding: 5px;"> CIB⁵ A 61 F, A 61 B </div> Documentation consultée autre que la documentation minimale dans la mesure où de tels documents font partie des domaines sur lesquels la recherche a porté ?		
III. DOCUMENTS CONSIDÉRÉS COMME PERTINENTS **		
Catégorie *	Identification des documents cités, ** avec indication, si nécessaire, des passages pertinents **	N° des revendications visées **
X	US, A, 4743260 (BURTON) 10 mai 1988 voir le document en entier	1-5
Y	--	7-10
Y	FR, A, 2275679 (CROCK et al.) 16 janvier 1976 voir page 4, lignes 18-35; figures 4-6	7-10
X	--	
X	EP, A, 0140790 (PEZE) 8 mai 1985 voir résumé; figure 3	1
A	--	
A	FR, A, 1240313 (JUDET) 25 juillet 1960 voir figures	1-4
A	--	
A	WO, A, 88/07357 (KLUGER) 6 octobre 1988	
<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <p>* Catégories spéciales de documents cités: ** -----</p> <p>« A » document définissant l'état général de la technique, non considéré comme particulièrement pertinent</p> <p>« E » document antérieur, mais publié à la date de dépôt international ou après cette date</p> <p>« L » document pouvant jeter un doute sur une revendication de priorité ou cité pour déterminer la date de publication d'une autre citation ou pour une raison spéciale (telle qu'indiquée)</p> <p>« O » document se référant à une divulgation orale, à un usage, à une exposition ou tous autres moyens</p> <p>« P » document publié avant la date de dépôt international, mais postérieurement à la date de priorité revendiquée</p> </div> <div style="width: 45%;"> <p>« T » document ultérieur publié postérieurement à la date de dépôt international ou à la date de priorité et n'appartenant pas à l'état de la technique pertinent, mais cité pour comprendre le principe ou la théorie constituant la base de l'invention</p> <p>« X » document particulièrement pertinent: l'invention revendiquée ne peut être considérée comme nouvelle ou comme impliquant une activité inventive</p> <p>« Y » document particulièrement pertinent: l'invention revendiquée ne peut être considérée comme impliquant une activité inventive lorsque le document est associé à un ou plusieurs autres documents de même nature, cette combinaison étant évidente pour une personne du métier.</p> <p>« Z » document qui fait partie de la même famille de brevets</p> </div> </div>		
IV. CERTIFICATION		
Date à laquelle la recherche internationale a été effectivement achevée <div style="text-align: center; font-size: 1.2em;">12 octobre 1990</div>		Date d'expédition du présent rapport de recherche internationale <div style="text-align: center; font-size: 1.2em;">30 OCT 1990</div>
Administration chargée de la recherche internationale <div style="text-align: center; font-weight: bold;">OFFICE EUROPEEN DES BREVETS</div>		Signature du fonctionnaire autorisé <div style="text-align: center; font-family: cursive;">MISS D. S. KONIAZNIK</div>

ANNEXE AU RAPPORT DE RECHERCHE INTERNATIONALE RELATIF A LA DEMANDE INTERNATIONALE NO.

FR 9000285
SA 36737

La présente annexe indique les membres de la famille de brevets relatifs aux documents brevets cités dans le rapport de recherche internationale visé ci-dessous.
Lesdits membres sont contenus au fichier informatique de l'Office européen des brevets à la date du 23/10/90.
Les renseignements fournis sont donnés à titre indicatif et n'engagent pas la responsabilité de l'Office européen des brevets.

Document brevet cité au rapport de recherche	Date de publication	Membre(s) de la famille de brevet(s)	Date de publication
US-A- 4743260	10-05-88	Aucun	
FR-A- 2275679	16-01-76	GB-A- 1519139	26-07-78
EP-A- 0140790	08-05-85	FR-A, B 2553993	03-05-85
		JP-A- 60111651	18-06-85
		US-A- 4697582	06-10-87
FR-A- 1240313		Aucun	
WO-A- 8807357	06-10-88	DE-A- 3711091	13-10-88
		EP-A- 0316371	24-05-89

EP1 9000285

Pour tout renseignement concernant cette annexe : voir Journal Officiel de l'Office européen des brevets, No.12/82